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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/447,227	11/22/1999	MARK C. SHULTS	MARKWELL-040	3546

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EXAMINER

NASSER, ROBERT L

ART UNIT	PAPER NUMBER
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3736

DATE MAILED: 04/04/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/447,227

Applicant(s)

SHULTS ET AL.

Examiner

Robert L. Nasser Jr.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12/27/2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 33-42, 48, 49 and 54-87 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 33-42, 48, 49 and 54-87 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>2/3/2006</u> . | 6) <input type="checkbox"/> Other: _____ |

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Claim 78 is objected to because the phrase "previously presented" has been entered into the claim.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 33-36, 48, 54, and 70-87 are rejected under 35 U.S.C. 103(a) as being obvious Rhodes et al WO 92/13271 in view of Picha 5706807. Rhodes shows a device in figure 2 including a housing that houses a sensor 30, 32 with an interface tip 36, with a distal first domain, i.e. surgical Dacron (polyester) fabric (see page 17 at the top) to support tissue ingrowth, a second domain, the outer membrane which is impermeable to macrophages (see page 7, lines 30-31 and pages 19+), which is made from silicone (page 22, line 16), a sensing membrane containing an enzyme (see page 7) lines 31 and 32) and a third layer that is an electrolytic phase, between the sensing layer and the sensor (see pages 7-8). Rhodes further teaches implanting the device wholly in a patient so as to elicit a foreign body capsule response, where the tip is anchored by means of a capsular attachment layer, the Dacron coating on the sides and bottom of the device. The angiogenic layer does not lie on the sensing surface. However, Picha shows a similar device where such an angiogenic layer surrounds the entire sensing area. As such, it would have been obvious to modify Rhodes et al to engulf the entire

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device in the Dacron, as it is merely the substitution of one known configuration for another. Claim 35 is rejected in that there is further an angiogenic layer, screen 46 treated with a angiogenesis factor. Claim 36 is rejected in that Dacron is non-smooth. Claims 70-72, and 76-78 are rejected for the reasons given above. Claim 85 is rejected in that the Dacron layer extends across a top surface of the device (depending on the orientation) and anchors the device in place. With respect to claims 73-75, the examiner takes official notice that it is known to explant the device when the useful life of the device is over. With respect to claims 80-83, the examiner takes official notice that all of the sensors recited are known glucose sensors. Hence, it would have been obvious to modify Gilligan et al to use any of the recited sensors, as it is merely the substitution of one known equivalent sensor for another.

Claims 38-42, 49, and 55-69 are rejected under 35 U.S.C. 103(a) as being obvious over Rhodes et al WO 92/13271 in view of Allen et al 5322063. Rhodes shows a device in figure 2 including a housing that houses a sensor 30, 32 with an interface tip 36, with a distal first domain, i.e. surgical Dacron (polyester) fabric (see page 17 at the top) to support tissue ingrowth, a second domain, the outer membrane which is impermeable to macrophages (see page 7, lines 30-31 and pages 19+), which is made from silicone (page 22, line 16), a sensing membrane containing an enzyme (see page 7) lines 31 and 32) and a third layer that is an electrolytic phase, between the sensing layer and the sensor (see pages 7-8). Rhodes further teaches implanting the device wholly in a patient so as to elicit a foreign body capsule response, where the tip is anchored by means of a capsular attachment layer, the Dacron coating on the sides

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and bottom of the device. The sensing membrane does not extend outwardly from the housing. However, Allen et al shows exactly such an arrangement. Hence, it would have been obvious to modify Rhodes to use to configuration of Allen et al, as it is merely the substitution of one known equivalent arrangement for another. In addition, the layer 46 is a vascularization promoting layer. Claim 42 is rejected in that the device includes a transmitter for transmitting data to the exterior of the body(see page 15, line 9). Claim 49 is rejected in that the enzyme used is glucose oxidase. With respect to claims 56-58, it is the examiner's position that given that the device has the same structure as the claimed invention, it would measure glucose accurate for the time periods. Claim 62 is rejected in that the first domain stabilizes over time. With respect to claims 59-61, the examiner takes official notice that it is known to explant the device when the useful life of the device is over. With respect to claims 66-69 the examiner takes official notice that all of the sensors recited are known glucose sensors. Hence, it would have been obvious to modify Rhodes to use any of the recited sensors, as it is merely the substitution of one known equivalent sensor for another.

Claims 37 and 87 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rhodes et al in view Picha, as applied to claims 33-36, 48, 54, and 70-87 above, further in view of the Gilligan et al article entitled "Evaluation of a Subcutaneous Glucose Sensor out to 3 months in a dog model." Gilligan further teaches that the Dacron jacket can be made from a Dacron velour. Hence, it would have been obvious to modify Rhodes to use such a layer, as it is merely the substitution of one known material for another.

Applicant's arguments filed 12/27/2005 have been fully considered but they are moot in view of the new grounds of rejection.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert L. Nasser Jr. whose telephone number is 571 272-4731. The examiner can normally be reached on 9:30 - 6pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenberg can be reached on 571 272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

RLN
March 29, 2006

Robert S. Messer
[Signature]